TABLE—FLAGGING CRITERIA—Continued

| Toxicity studies | Pesticide assessment guidelines No. | Criteria | Reporting code |
|---|---|---|---|
| or<br>Subchronic feeding study | 82–1 | An incidence of neoplasms in male or female animals which increases with dose;<br>or<br>A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex;<br>or<br>An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals<br>or<br>A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals | 1<br><br>2<br><br>3<br><br>4 |
| Teratogenicity | 83–3 | When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels | 5 |
| Neurotoxicity | 81–7 | When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity | 6 |
| Chronic feeding study or combined chronic feeding/oncogenicity study | 83–1 | Cholinesterase inhibition NOEL less than 10 times the current existing ADI.<br>or<br>General (systemic) toxicity NOEL less than 100 times the current existing ADI. | 7<br><br>8 |
| Reproduction study | 83–4 | Reproductive effects NOEL less than 100 times the current ADI | 9 |
| Subchronic feeding study | 82–1 | Cholinesterase inhibition NOEL less than 100 times the current existing ADI.<br>or<br>General (systemic) toxicity NOEL less than 1000 times the current existing ADI. | 10<br><br>11 |

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.''

(2) ''I have applied the criteria of 40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]''

[53 FR 15992, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

### § 161.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in §161.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to consult with the Product Manager for

his product to resolve questions relating to the protocols or the data requirements before undertaking extensive testing under § 161.40.

(b) Any applicant who believes that a data requirement is inapplicable to a specific pesticide product may request a waiver of a data requirement under § 161.45.

(c) The Agency may require an applicant to provide additional data or information beyond that specified in subparts C and D of this part when these data are not sufficient to permit EPA to evaluate the applicant's product under § 161.75.

(d) Several policies are in effect that govern the data requirements for registration of products having minor uses. These policies reduce substantially the data requirements that need to be met on the basis of limited exposures and economic equity, and allow case-by-case decision making to determine the specific needs for each kind of use under § 161.60.

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator ''shall revise such guidelines from time to time.'' Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies under § 161.80.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

### § 161.40 Consultation with the Agency.

This part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product's use pattern or composition may result in the need for conferences between registration applicants and the Agency. Such conferences may be initiated by the Agency or by registration applicants. Applicants are expected to contact their respective Product Managers to arrange discussions. The Agency welcomes suggestions for changes to improve the clarity, accuracy, or some other aspect of the data requirements set forth in this part. Specific suggestions should be forwarded to the Director of the Hazard Evaluation Division.

### § 161.45 Waivers.

(a) *Rationale and policy.* (1) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(2) The Agency will waive data requirements on a case-by-case basis in response to specific written requests by applicants. Because of the wide variety of types and use patterns of pesticides, it is impossible to spell out all of the circumstances which might serve as a basis for waiving data requirements. The Agency, however, will take into account, as appropriate, the factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request.

(2) To request a waiver, an applicant must submit a written request to the appropriate Product Manager. The request must specifically identify the data requirement for which a waiver is requested, explain why he thinks data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which he believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) *Notification of waiver decision.* The Agency will review each waiver request and inform the applicant in writing of its decision. In addition, for decisions